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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/422,804	10/22/1999	EDWIN SOUTHERN	00263/PP/IR	6012

7590 10/26/2006

Wenderoth, Lind & Ponack
2033 K street N.W
Washington, DC 20006

EXAMINER	
BRUSCA, JOHN S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/422,804	SOUTHERN, EDWIN	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-99* is/are pending in the application.

4a) Of the above claim(s) *40-95* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-19,21-26,38,39 and 96-99* is/are rejected.

7)☒ Claim(s) *20 and 27-37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. PCT/GB89/00460.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/8/05, 12/20/05,*. 8/10/2006
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply*.

Information Disclosure Statement

1. The references indicated as not considered due to no publisher in the information disclosure statements filed 08 December 2005 and 20 December 2005 in the Office action mailed 10 February 2006 have now been considered in view of 37 CFR 1.98(a)(1) which states that one of the categories of the categories of documents suitable for listing in an Information Disclosure Statement is "other information." A signed copy of the list of references has been attached to this Office action. References previously considered have been lined through on the attached copy of the list of references to avoid duplications in the lists of considered references in the application file.

Specification

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

Nucleic acid sequences appear on page13, 14, and 21 of the specification but applicants have not submitted a Sequence Listing as set forth in 37 CFR § 1.821 (see MPEP § 2422).

Applicants are required to comply with all of the requirements of 37 CFR § 1.821 through 1.825. Any response to this office action which fails to meet all of these requirements will be considered non-responsive. The Applicant's attention is directed to the attached Notice to Comply with the Sequence Rules. The nature of the sequences disclosed in the instant application has allowed an examination on the merits, the results of which are communicated below.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the

reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

5. Claims 17, 20, 25, 26, and 39 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-33 and 43-68 of copending Application No. 10/115077. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are either species of the instant claims or have only minor differences.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 17, 19, 21-24, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Stavrianopoulos et al. (reference KB in the Information Disclosure Statement filed 08 December 2005)

The claims are drawn to arrays of oligonucleotides comprising different known oligonucleotides at different positions. In some embodiments the array has a glass substrate. In some embodiments the oligonucleotides are attached to the support by a covalent linkage.

Regarding the limitations of claims 23 and 24, it is brought to the Applicant's attention that a product by process claim is examined for novelty and obviousness of the claimed product only, and that no consideration is given to the novelty or obviousness of the method of making the claimed product. See M.P.E.P. 2113.

Stavrianopoulos et al. shows in column 1, lines 29-30, and column 5 an array of oligonucleotides, with a substrate that may be plastic or glass. Stavrianopoulos et al. shows in column 8, lines 40-45 that various (meaning different) polynucleotide samples may be present in the array.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 17, 18, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stavrianopoulos et al. in view of Cooke et al.

The claims are drawn to arrays of oligonucleotides comprising different known oligonucleotides at different positions. In some embodiments there are at least 72 samples in the array.

Stavrianopoulos et al. shows in column 1, lines 29-30, and column 5 an array of oligonucleotides, with a substrate that may be plastic or glass. Stavrianopoulos et al. shows in column 8, lines 40-45 that various (meaning different) polynucleotide samples may be present in the array. Stavrianopoulos et al. shows use of conventional microtiter plates to contain the samples in columns 12, lines 20-24. Stavrianopoulos et al. does not show the number of wells that exist in conventional microtiter plates.

Cooke et al. shows microtiter plates that differ from the conventional plates by virtue of being made from disposable plastic. Cooke et al. shows in figure 1 a microtiter plate with an 8x12 matrix of wells for a total of 96 wells.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Stavrianopoulos et al. by use of the 96 well microtiter plate of Cooke et al. for the purpose of analyzing up to 96 samples in one array.

10. Claims 17 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stavrianopoulos et al. in view of Suggs et al.

The claims are drawn to arrays of oligonucleotides comprising different known oligonucleotides at different positions. In some embodiments the oligonucleotides in the array are between 8 and 20 nucleotides in length.

Stavrianopoulos et al. shows in column 1, lines 29-30, and column 5 an array of oligonucleotides, with a substrate that may be plastic or glass. Stavrianopoulos et al. shows in column 8, lines 40-45 that various (meaning different) polynucleotide samples may be present in the array. Stavrianopoulos et al. shows use of conventional microtiter plates to contain the samples in columns 12, lines 20-24. Stavrianopoulos et al. shows that the applied samples may

be of small or high molecular weight in column 1, lines 29-30. Stavrianopoulos et al. shows in column 5, lines 63-67 that oligonucleotides used to hybridize to the samples on the array should be at least 25 nucleotides in length to allow for stable hybridization with the complementary nucleotides of the sample on the array. Stavrianopoulos et al. does not show use of samples on an array of between 8 and 20 nucleotides in length.

Suggs et al. shows in the abstract , methods section on page 6613 and Table 1 the synthesis and use of oligonucleotide probes that are 15 nucleotides in length. Suggs et al. shows in figures 1 and 2 that such probes may be used to hybridize specifically to a complementary sequence.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Stavrianopoulos et al. by use of the 15mer probes of Suggs et al. because Suggs et al. shows that oligonucleotides of that length are long enough to allow for specific hybridization and a functional equivalent to longer oligonucleotides, and further obvious because shorter oligonucleotides allow for reduced labor and cost for synthesis.

11. Claims 96, 98, and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stavrianopoulos et al. in view of Caulfield et al.

The claims are drawn to kits comprising arrays of oligonucleotides comprising different known oligonucleotides at different positions and scanners for detecting hybridization to the array.

Stavrianopoulos et al. shows in column 1, lines 29-30, and column 5 an array of oligonucleotides, and shows a microtiter substrate in column 12, lines 20-24. Stavrianopoulos et al. shows in column 8, lines 40-45 that various (meaning different) polynucleotide samples may

be present in the array. Stavrianopoulos et al. shows colorimetric assays of hybridization in column 6-7 and table 1. Stavrianopoulos et al. does not show computer controlled scanners of colorimetric assays.

Caulfield et al. shows in the abstract and throughout a computer controlled analysis of a microtiter assay result. Caulfield et al. shows in the methods section on page 207 that an automatic scanner/reader was used to determine the level of colored product in each well of a microtiter assay, and further shows throughout the paper a computer mediated analysis of the results of the assay.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assay of Stavrianopoulos et al. by use of the computer mediated automatic scanning and raw data analysis of Caulfield et al. to save manual labor of analyzing the results of a colorimetric microtiter assay.

12. Claim 97 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stavrianopoulos et al. in view of Cooke et al. as applied to claims 17, 18, and 38 above, and further in view of Caulfield et al.

The claims are drawn to a kit comprising arrays of oligonucleotides comprising at least 72 different known oligonucleotides at different positions and scanners for detecting hybridization to the array.

Stavrianopoulos et al. in view of Cooke et al. as applied to claims 17, 18, and 38 above does not show computer mediated automatic scanning and raw data analysis of a colorimetric microtiter assay.

Caulfield et al. shows in the abstract and throughout a computer controlled analysis of a microtiter assay result. Caulfield et al. shows in the methods section on page 207 that an automatic scanner/reader was used to determine the level of colored product in each well of a microtiter assay, and further shows throughout the paper a computer mediated analysis of the results of the assay.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assay of Stavrianopoulos et al. in view of Cooke et al. as applied to claims 17, 18, and 38 above by use of the computer mediated automatic scanning and raw data analysis of Caulfield et al. to save manual labor of analyzing the results of a colorimetric microtiter assay.

13. Claims 17 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stavrianopoulos et al. in view of Molecular Biosystems Inc. (WO 85/01051, reference AF in the Information Disclosure Statement filed 08 December 2005).

The claims are drawn to arrays of oligonucleotides comprising different known oligonucleotides at different positions. In some embodiments the oligonucleotide is covalently linked to the support.

Stavrianopoulos et al. shows in column 1, lines 29-30, and column 5 an array of oligonucleotides, with a substrate that may be plastic or glass. Stavrianopoulos et al. shows in column 8, lines 40-45 that various (meaning different) polynucleotide samples may be present in the array. Stavrianopoulos et al. does not show covalent linkage of oligonucleotides to supports.

Molecular Biosystems Inc. shows covalent linkages of oligonucleotides to a solid support and use of such linked oligonucleotides for hybridization assays in pages 8-9, and 34-37.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the hybridization assay of Stavrianopoulos et al. by use of the covalent linkage of Molecular Biosystems Inc. because Molecular Biosystems Inc. shows that such covalent linkages are useful to tether hybridized polynucleotide duplexes for purification of the hybridized duplex in hybridization assays.

Response to Arguments

14. Applicant's arguments filed 10 August 2006 regarding the prior art rejections have been fully considered but they are not persuasive.

The limitation in the claimed subject matter that the compositions comprise oligonucleotides containing predetermined sequences is not given patentable weight. The limitation refers to prior knowledge regarding the structure of the claimed composition, which is equivalent to a product by process limitation. It is brought to the Applicant's attention that a product by process claim is examined for novelty and obviousness of the claimed product only, and that no consideration is given to the novelty or obviousness of the method of making the claimed product. See M.P.E.P. 2113. Regarding the instant claimed subject matter the claimed prior knowledge does not affect the structure of the claimed composition and the rejections detailed above are maintained. It is further noted that Stavianopoulos et al. used predetermined oligonucleotides in their described arrays, and the predetermined oligonucleotides would inherently have a sequence of nucleotides. Therefore the inherent sequence of the oligonucleotides of Stavrianopoulos et al. was predetermined by the choice of oligonucleotide used in the array, even if the sequence was not known. The applicants further argue that the

samples of Stavrianopoulos et al are on different wells and are therefore on different surfaces, however a microtiter dish is a single surface comprising multiple depressions.

Allowable Subject Matter

15. Claims 20 and 27-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.S. Brusca 22 October 2006

John S. Brusca
Primary Examiner
Art Unit 1631

jsb

NOTICE TO COMPLY WITH SEQUENCE RULES	Application No. 09/422,804	Applicant(s) SOUTHERN, EDWIN	
	Examiner John S. Brusca	Art Unit 1631	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reasons:

☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing in computer readable form has been submitted. However the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked up "Raw Sequence Listing".

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable. A Substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☐ 7. Other:

Applicant must provide:

☒ An initial or ☐ A substitute computer readable form copy of the Sequence Listing.

☒ An initial or ☐ A Substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same, and, where applicable, include no new matter, as required by 37 CFR 1.821(e), (f), or (g) or 1.825(b) or (d).

FOR QUESTIONS PLEASE CONTACT:

Rules Interpretation (703) 308-4216
CRF Submission Help (703) 308 4212
PatentIn software help (703) 308 6856

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